

03-24-04

10/14



Docket No. JAB 1425 CON 1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Bart De Corte, *et al.*  
Serial No. : 10/634,682 Art Unit: 1614  
Filed : August 5, 2003 Examiner:  
For : HIV replication inhibiting pyrimidines

I hereby certify that this correspondence is being deposited with the United States Postal Service U.S. Express Mail No. EU642139625US in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on

March 23, 2004  
(Date of Deposit)

Jesús Juanós i Timoneda  
(Name of applicant, assignee, or Registered Representative)

  
(Signature)

March 23, 2004  
(Date of Signature)

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.



This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ /

the fee of \$180.00 as set forth in §1.17(p).

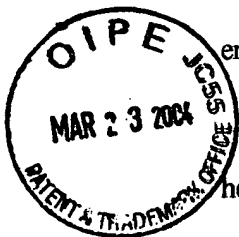
☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ /

the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).



☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are not enclosed herewith pursuant to 37 C.F.R. § 1.98(d)(1)-(2):

☒ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner because such references were filed in US Ser. No. 09/430,966, filing date November 1, 1999, of which the present application is a continuation, copies of the references are not enclosed herewith.

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached is a Submission Under MPEP 609 D, which references were listed in the corresponding patent applications.

☐ In view of the likelihood that these references are available to the Examiner, copies of the references are not enclosed herewith.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.



Please charge any deficiency or credit any overpayment to Deposit Account No. 10-

0750/JAB1425 CON 1/JJiT. This form is submitted in triplicate.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "Jesús Juanos i Timoneda", written over a horizontal line.

Jesús Juanos i Timoneda

Reg. No. 43,332

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DATED: March 23, 2004



PTO/SB/08A (08-00)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/634,682
Filing Date	08/05/2003
First Named Inventor	Bart De Corte
Group Art Unit	1614
Examiner Name	
Attorney Docket Number	JAB 1425 Con 1

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Misc.
		Number	Kind Code <sup>2</sup> (if known)			
	1	4,659,363		Hubele et al.	04-21-1987	Priority to same application as EP 0945443 listed below.
	2	5,691,364		Buckman et al.	11-25-1997	
	3	6,048,866		Hutchings et al.	04-11-2000	
	4	6,093,716		Davis et al.	07-25-2000	
	5	6,197,779	B1	Andries et al.	03-06-2001	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Translation	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
	6	EP	0945443	A1	JANSSEN PHARMACEUTICA, NV	09-29-1999	No	
	7	WO	98/41512	A1	CELLTECH THERAPEUTICS, LTD	09-24-1998	No	
	8	EP	0945442	A1	JANSSEN PHARMACEUTICA, NV	09-29-1999	No	
	9	WO	95/10506	A1	DU PONT MERCK PHARMACEUTICAL	04-20-1995	No	
	10	EP	0371139	B1	MIYASAKA, Tadashi	10-12-1994	No	
	11	EP	0135472	A2	CIBA-GEIGY A.G.	03-27-1985	No	
	12	EP	0 588 762	A1	CIBA-GEIGY A.G.	08-23-1993	Yes	
	13	EP	0 135 472	A2	CIBA-GEIGY A.G.	07-19-1984	English Abstract	
	14	EP	0834,507	A1	JANSSEN PHARMACEUTICA, NV	04-08-1998	No	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. <sup>6</sup> 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 2 of 3

Application Number	10/634,682
Filing Date	08/05/2003
First Named Inventor	Bart De Corte
Group Art Unit	1614
Examiner Name	
Attorney Docket Number	JAB 1425 Con 1

**OTHER - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Translation	T <sup>2</sup>
	15	ARNOLD, et al., Inhibitor conformational flexibility and positional variation are important for activity against drug-resistant virus: crystal structures of highly potent non-nucleoside inhibitors of HIV-1 reverse transcriptase, 21 <sup>st</sup> European Crystallographic Meeting, Durban, South Africa, 24-29, Aug. 2003.		
	16	ARNOLD, Conformational Flexibility of DAPYs: activity against resistant HIV, Aug. 2003.		
	17	BLAGOVIĆ, et al., Validation of a Model for the Complex of HIV-1 Reverse Transcriptase with Nonnucleoside Inhibitor TMC125, J. AM. CHEM. SOC. 2003, Vol. 125, pp. 6016-6017.		
	18	CLARK, Inhibitor conformational flexibility and positional variation are important for activity against drug-resistant virus: crystal structures of highly potent non-nucleoside inhibitors of HIV-1 reverse transcriptase, 21 <sup>st</sup> European Crystallographic Meeting, Durban, S. Africa, 24-29, Aug. 2003.		
	19	DAS, et al., Could multiple modes of binding of a potent NNRTI TMC125-R165335 explain its potency against common drug-resistant mutants?, CROI, Boston, Feb. 2003		
	20	M-P de BETHUNE, TMC 125 resistance profiles, Resistance, Mexico, June 2003		
	21	FURUKAWA, et al., Syntheses of Compounds related to Guanidine and their Inhibitory Action on Growth of HeLa Cells, Chem. Pharm. Bull. 9 (11), 914-921 (1951)		
	22	GAZZARD, et al., TMC125, A Next-Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI, CROI, Seattle, Feb. 2002.		
	23	GAZZARD, et al., An open-label assessment of TMC 125 - a new, next-generation NNRTI, for 7 days in HIV-1 infected individuals with NNRTI resistance, AIDS 2003, Vol. 17, pp. 49-54.		
	24	GAZZARD, et al., TMC125, a Next Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI-Resistance, XIV International AIDS Conference, July 7-11, 2003, Barcelona, Spain		
	25	GAZZARD, TMC 125 C207 study treatment-experienced, CROI Seattle, Feb. 2002		
	26	GAZZARD, 7 day treatment-experienced, WAC Barcelona, Jul. 2002		
	27	GRUZDEV, et al., A Randomized, double-blind, placebo-controlled trial of TMC125 as 7-day monotherapy in antiretroviral naïve HIV-1 infected subjects, AIDS 2003, VOL 17, pp. 2487-2494.	No	
	28	GULICK, New Antiretroviral Drugs, Clinical Microbiology and Infectious Diseases, CMI, 9, (3) pp. 186-193 (March, 2003)		
	29	LANGE, TMC 125 decay rate vs ERA, CROI Seattle, Feb. 2002		
	30	LEWI, Potency & multiple binding modes of TMC 125, CROI Boston, Feb. 2003		
	31	LUDOVICI, et al., Evolution of Anti-HIV Drug Candidates. Part 3: Diarylpyrimidine (DAPY) Analogues, Bioorganic & Medical Chemistry Letters 11, 2001, pp. 2235-2239.		
	32	SANKATSING, et al., TMC 125 Monotherapy for One Week Results in a Similar Initial Rate of Decline of HIV-1 RNA as Therapy With a 5-Drug Regimen, CROI, Seattle, Feb., 2002.		
	33	SANKATSING, et al., TMC125 exerts similar initial antiviral potency as a five-drug, triple class antiretroviral regimen, AIDS 2003, Vol. 17, pp. 2623-2627.		

Examiner Signature		Date Considered	
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